REMARKS

Rejection of claims 66 to 82 under 35 U.S.C. § 102(e) as being anticipated by Ebner, *et al.*, U.S. 2003/0092133

Pursuant to Applicants' response filed April 29, 2004 the final rejection under § 102(e) of claims 66 to 82 over US 2003/0003545 ("the '545 publication") was removed. However, in the June 21, 2004 Office Action, claims 66 to 82 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. 2003/0092133 ("the '133 publication"), a divisional of the '545 publication. The Examiner states that the instant rejection is made for the same reasons set forth in the previous Office Action, Paper No. 16, mailed on February 24, 2003 at page 3 because the '133 publication has the same disclosure as that of '545 publication. Applicants would also like to point out that the '133 and '545 publications claim priority, under § 119(e), to the same three provisional applications--No. 60/087,340, filed May 29, 1998; No. 60/099,805, filed Sept. 10, 1998; and No. 60/131,965, filed April 30, 1999.

Accordingly, the Examiner maintains that the '133 publication, "disclose a polypeptide of IL-21, which has the same amino acid sequence of SEQ ID NO:29, and is identical to SEQ ID NO:3 of the present invention." *See* page 2 of Office Action dated June 4, 2003, incorporating views expressed on pages 2 and 3 of Office Action dated February 24, 2003. The Examiner further asserts that the '133 publication teaches a pharmaceutical composition comprising the polypeptide and a kit comprising the composition and therefore, anticipates claims 66-80. *See* page 3 of the Office Action dated February 24, 2003. The Examiner also notes that the functional limitations of the claims are "either an inherent property of the same composition, or an intended use of the claimed composition, and do not alter the nature of the claimed composition." Finally, the examiner rejected claims 81 and 82 under 35 U.S.C. § 102(e) based on the '133 publication's disclosure of a fusion protein comprising said polypeptide fused to antibody domains such as an antibody Fc region. *See* page 3 of the February 24, 2003 Office Action.

Applicants respectfully traverses this rejection.

As an initial point, Applicants note that the first of the three provisional applications to which the '133 publication claims priority under 35 U.S.C. § 119(e) does not, in fact, even disclose the polypeptide sequence cited by the Examiner (i.e., SEQ. ID NO:29). The sequence

labeled as SEQ ID NO:29 in the '133 publication first appeared in the provisional application filed on September 10, 1998; namely, provisional application no. 60/099,805 (the '805 application). As such, the '133 publication's disclosure cannot be given a prior art effective date under § 102(e) for the recited sequences (SEQ ID NO:29) as of the first-claimed filing date of the '340 application (i.e., May 29, 1998). The Examiner has agreed to this point. See Office Action dated February 10, 2004.

Applicants note that it is well-settled law that a patent (and, by implication, a patent application published pursuant to 35 U.S.C. § 122(b)) shall have effect under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter in question. If the patent or published application claims the benefit under 35 U.S.C. § 120 (and by implication under 35 U.S.C. § 119(e)) to an earlier filed application, that patent or published application shall not be entitled to prior art effect under § 102(e) if the earlier filed application does not provide a sufficient disclosure under 35 U.S.C. § 112, first paragraph for the subject matter in question. To be given effect under § 102(e), the claims of the reference patent must be supported in the manner required by 35 U.S.C. § 112 in the priority application whose date is relied on to establish the prior art status of the patent. *See In re Wertheim*, 646 F2d 527, 209 USPQ 554 (CCPA 1981); and MPEP 2136.03, sub-heading IV.

Applicants direct the Examiner's attention to the previously-presented declaration submitted pursuant to 37 CFR § 1.131, executed by the inventors of the present application, and provided herewith. As noted above, the '133 publication claims priority to the same provisional applications and has the same disclosure as the '545 publication referred to in the declaration. Accordingly, Applicants submit that the declaration effectively antedates the '133 publication for the same reasons as the '545 publication, particularly in view of the observations provided above which establish that the '133 publication is not entitled to a prior art date pursuant to 35 U.S.C. 102(e) of May 29, 1998 (i.e., the filing date of the '340 application).

Accordingly, Applicants submit that the '133 publication is not prior art to the present claims under § 102(e) and as such, cannot be relied upon to support a § 102(e) rejection of said claims. *See* MPEP § 2136.05. Applicants respectfully request the Examiner to withdraw the rejection of claims 66 to 82 under § 102(e) based on the '133 publication.

Additional Comments

Applicants have not enclosed copies of the applications referred to in the declaration submitted pursuant to 37 CFR § 1.131 but will do so upon request. Applicants note that the applications were provided with the § 131 declaration as submitted in Applicants' response dated October 31, 2003.

In view of this response, Applicants submit that the present application is in condition for allowance and should be passed to issue. If, however, the Examiner believes that the rejection cannot be removed in light of the § 131 declaration evidence, Applicants request that the Examiner declare an interference between the instant application and the '133 publication (U.S.S.N. 10/153,770). See MPEP § 2303. Applicants note that unless the current rejection is removed or an interference is declared between the two applications, Applicants have no process by which to continue the prosecution of the current invention and will be improperly precluded from demonstrating their entitlement thereto.

Respectfully submitted,
for GENENTECH, INC.

David A. Steffes
Registration No. 46,042

Date: December 21, 2004